10/507485

Patent
Attorney's Docket No. 1032013-000103

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of

Avraham Cohen et al.

Patent No.: 7,034,038

Issued: April 25, 2006

Title: ENANTIOMER (-) OF TENATOPRAZOLE AND THE THERAPEUTIC USE THEREOF

REQUEST FOR CERTIFICATION OF CORRECTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Issuance of a Certificate of Correction for the above-captioned patent is respectfully requested in accordance with the accompanying Form PTO-1050 (submitted in duplicate).

☐ The requisite government fee of $ 100:

☐ is submitted herewith;
☐ is authorized to be charged to Deposit Account No. 02-4800; or
☐ charge to credit card. Form PTO-2038 is attached.

☒ It is believed that payment of a fee is unnecessary.

A typographical error was made by the Patent Office during the printing of the subject patent. A copy of the Amendment Under 37 C.F.R. § 1.312, filed January 6, 2006, is enclosed showing the correct text.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. § 1.20(a) that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: August 18, 2006

By: _____
Melissa M. Hayworth
Registration No. 45774

P.O. Box 1404
Alexandria, VA 22313-1404
703 836 6620

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of)
)
Avraham Cohen et al.)
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Patent No.: 7,034,038)
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BUCHANAN INGERSOLL & ROONEY PC

Date: August 18, 2006

By: _____
Melissa M. Haywood
Registration No. 45774

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703 836 6620

PTO/SB/44 (08-00) (Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,034,038
DATED : April 25, 2006
INVENTOR(S) : Avraham Cohen et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 9, line 59, please delete "(+)" and insert --(-)-- in place thereof.

MAILING ADDRESS OF SENDER:

BUCHANAN INGERSOLL & ROONEY PC
P.O. Box 1404
Alexandria, Virginia 22313-1404

PATENT NO. 7,034,038

No. of additional copies

→

SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Patent

Attorney Docket No. 032013-103

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop Issue Fee

In re Patent Application of
Suzy Charbit et al.
Application No.: 10/507,485
Filing Date: January 31, 2005

Group Art Unit: 1625
Examiner: D. MARGARET M. SEAMAN
Confirmation No.: 8571

Title: ENANTIOMER (-) OF TENATOPRAZOLE AND THE THERAPEUTIC USE THEREOF

AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a reply for the above-identified patent application.

☐ A Petition for Extension of Time is also enclosed.

☐ Terminal Disclaimer(s) and the ☐ $65.00 (2814) ☐ $130.00 (1814) fee per Disclaimer due under 37 C.F.R. § 1.20(d) are also enclosed.

☐ Also enclosed is/are _____

☐ Small entity status is hereby claimed.

☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the ☐ $395.00 (2801) ☐ $790.00 (1801) fee due under 37 C.F.R. § 1.17(e).

☐ Applicant(s) requests that any previously unentered after final amendments not be entered. Continued examination is requested based on the enclosed documents identified above.

☐ Applicant(s) previously submitted _____
on _____,
for which continued examination is requested.

☐ Applicant(s) requests suspension of action by the Office until at least _____, which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R. § 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.

☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also enclosed.

☒ No additional claim fee is required.

☐ An additional claim fee is required, and is calculated as shown below.

AMENDED CLAIMS					
	No. of Claims	Highest No. of Claims Previously Paid For	Extra Claims	Rate	Additional Fee
Total Claims	25	MINUS 30 =	0	x $50.00 (1202) =	$ 0.00
Independent Claims	8	MINUS 9 =	0	x $200.00 (1201) =	$ 0.00
If Amendment adds multiple dependent claims, add $360.00 (1203)					
Total Claim Amendment Fee					$ 0.00
☐ Small Entity Status claimed - subtract 50% of Total Claim Amendment Fee					$ 0.00
TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT					$ 0.00

☐ A check in the amount of _____ is enclosed for the fee due.

☐ Charge _____ to Deposit Account No. 02-4800.

☐ Charge _____ to credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BUCHANAN INGERSOLL PC

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

By _____
Melissa M. Hayworth
Registration No. 45,774

Date: January 6, 2006

Patent
Attorney's Docket No. 032013-103

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	**Mail Stop Issue Fee**
Suzy Charbit et al.	Group Art Unit: 1625
Application No.: 10/507,485	Examiner: D. MARGARET M. SEAMAN
Filed: January 31, 2005	Confirmation No.: 8571
For: ENANTIOMER (-) OF TENATOPRAZOLE AND THE THERAPEUTIC USE THEREOF	

AMENDMENT UNDER 37 C.F.R. § 1.312

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The present application has been allowed pursuant to a Notice of Allowance mailed December 19, 2005. The issue fee has not yet been paid.

In accordance with 37 C.F.R. § 1.312(a), Applicants respectfully request amendment of the abstract and claims as follows.

AMENDMENT TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Currently Amended) The compound (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~, or one of its salts, substantially free of the (+) enantiomer.

2. (Currently Amended) A pharmaceutical composition comprising (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~, or a pharmaceutically acceptable salt thereof, substantially free of the (+) enantiomer, and one or more pharmaceutically acceptable excipients or substrates.

3. (Currently Amended) The pharmaceutical composition according to claim 2, wherein the (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl] imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ is a pharmaceutically acceptable salt selected from the group consisting of alkaline and earth-alkaline metal salts.

4. (Currently Amended) The pharmaceutical composition according to claim 3, wherein the (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl] imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ is a pharmaceutically acceptable salt selected from the group consisting of sodium, potassium, lithium, magnesium and calcium salts.

5. (Currently Amended) The pharmaceutical composition according to claim 2, comprising a unitary dose comprising from about 10 mg to about 80 mg of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~.

6. – 13. (Canceled)

14. (Currently Amended) The pharmaceutical composition according to claim 3, comprising a unitary dose comprising from about 10 mg to about 80 mg of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~.

15. (Currently Amended) The pharmaceutical composition according to claim 4, comprising a unitary dose comprising from about 10 mg to 80 mg of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~.

16. (Currently Amended) A method of treatment of digestive diseases and conditions comprising administering to a subject in need thereof an effective amount of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer, or a pharmaceutically acceptable salt thereof,

wherein the digestive diseases and conditions are selected from the group consisting of Barrett's syndrome, Zollinger-Ellison syndrome, and atypical and oesophageal symptoms of gastro-oesophageal reflux.

17. (Canceled)

18. (Currently Amended) A method for the treatment of digestive diseases and conditions comprising administering to a subject in need thereof an effective amount of a pharmaceutical composition comprising (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-~~

~~2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ or a pharmaceutically acceptable salt thereof, substantially free of the (+) enantiomer, and one or more pharmaceutically acceptable excipients or substrates,

wherein the digestive diseases and conditions are selected from the group consisting of Barrett's syndrome, Zollinger-Ellison syndrome, atypical and oesophageal symptoms of gastro-oesophageal reflux.

19. (Canceled)

20. (Currently Amended) A method of treatment of an ulcer resulting from an infection by *Helicobacter pylori* comprising administering to a subject in need thereof an effective amount of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl] sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer, or a pharmaceutically acceptable salt thereof.

21. (Currently Amended) A method of treatment of an ulcer resulting from an infection by *Helicobacter pylori* comprising administering to a subject in need thereof an effective amount of a pharmaceutical composition comprising (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ or a pharmaceutically acceptable salt thereof, substantially free of the (+) enantiomer, and one or more pharmaceutically acceptable excipients or substrates.

22. (Currently Amended) A method of treating or preventing the relapse of oesophagitis comprising administering to a subject in need thereof an effective amount of a pharmaceutical composition comprising (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ or a pharmaceutically acceptable salt thereof, substantially free of the (+) enantiomer, and one or more pharmaceutically acceptable excipients or substrates.

23. (Currently Amended) A method of treating or preventing the relapse of oesophagitis comprising administering to a subject in need thereof an effective amount of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer, or a pharmaceutically acceptable salt thereof.

24. (Currently Amended) A method for the treatment of digestive diseases and conditions according to claim 16, wherein the effective amount of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer exhibits improved pharmacokinetic properties.

25. (Currently Amended) The method of claim 16, wherein the (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer or pharmaceutically acceptable salt thereof is administered orally.

26. (Currently Amended) The method of claim 16, wherein the (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~, substantially free of the (+) enantiomer or pharmaceutically acceptable salt thereof is administered via a parenteral solution.

27. (Previously Presented) The method of claim 25, wherein the oral administration is via tablet, capsule or oral suspension or oral emulsion.

28. (Previously Presented) The method of claim 26, wherein the parenteral administration is via an intravenous solution.

29. (Currently Amended) The method of claim 26, wherein the parenteral solution comprises a ~~tenatoprazole~~ salt of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine and a pharmaceutically acceptable substrate.

30. (Currently Amended) The method of claim 25, wherein the (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer is administered in an amount of about 10 mg to about 120 mg per day.

31. (Currently Amended) The method of claim 30, wherein the (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer is administered in an amount of about 10 mg to about 80 mg per day.

32. (Currently Amended) The method of claim 25, wherein the (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer is administered once per day.

33. (Currently Amended) The method of claim 25, wherein the (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer is administered once per day for a period of about four to about twelve weeks.

34. (Currently Amended) The method of claim 25, wherein the (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl]imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer is administered first via an intravenous route and subsequently via an oral route.

35. (Currently Amended) The method of claim 27, wherein the tablet is administered once per week and wherein the tablet comprises about 60 mg to about 90 mg of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]imidazol[4,5-b]pyridine ~~(-) 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfonyl] imidazol[4,5-b]pyridine~~ substantially free of the (+) enantiomer

36. (Canceled)

37. (Canceled)